

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: May, Michael J. et al.

Serial No.: 09/847946

Filed: May 2, 2001

For: ANTI-INFLAMMTORY COMPOUNDS AND

USES THEREOF

Attorney Docket No.: PPI-119

Group Art Unit: 1646

Examiner: Not Yet Assigned

RECEIVED

MAY 1 3 2003

TECH CENTER 1600/2900

Mail Stop DD Commissioner for Patents P.O. Box 1450 Alexandria, VA 22202

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop DD, P.O. Box 1450, Alexandria, VA 22202 on the date set forth below.

May 2, 2003

Date of Signature and of Mail Deposit

By:

Giulio A. Decenti, Jr.

Registration No. 31,503

Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. Reference ID Nos. A14, B3, B12, and C4 were cited in an International Search Report dated May 6, 2002 during the prosecution of PCT/US01/14346 which corresponds to the above referenced application. A copy of the report and each cited publication is enclosed.

Serial Number: 09/847946 Page -2-Group Art Unit: 1646

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed per se as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Giulio A. DeConti, Jr.

Registration No. 31,503 Attorney for Applicants

28 State Street Boston, MA 02109 (617) 227-7400

Date: May 2, 2003

GAD/AEM/MCL/MCA/krj

Enclosures



COUNSELLORS AT LAW 28 STATE STREET

BOSTON, MASSACHUSETTS 02109-1784 TELEPHONE (617) 227-7400 FAX (617) 742-4214 lc@lahive.com

JOHN A. LAHIVE, JR. (1928-1997) THOMAS V. SMURZYNSKI RALPH A. LOREN GIULIO A. DeCONTI, JR. ANN LAMPORT HAMMITTE ELIZABETH A. HANLEY AMY BAKER MANDRAGOURAS ANTHONY A. LAURENTANO KEVIN J. CANNING JANE E. REMILLARD DeANN FORAN SMITH PETER C. LAURO DEBRA J. MILASINCIC, Ph.D. DAVID J. RIKKERS DAVID R. BURNS JOHN S. CURRAN SEAN D. DETWEILER MEGAN E. WILLIAMS, Ph.D.

LISA M. DIROCCO HATHAWAY P. RUSSELL * MARIA LACCOTRIPE ZACHARAKIS, Ph.D. VINCENT P. LOCCISANO MERIDETH C. ARNOLD DANIELLE L. HERRITT EUIHOON LEE *

SENIOR COUNSEL JAMES E. COCKFIELD

OF COUNSEL JEREMIAH LYNCH WILLIAM A. SCOFIELD, JR. SIBLEY P. REPPERT JEANNE M. DIGIORGIO CYNTHIA L. KANIK, Ph.D.

May 2, 2003

PATENT AGENTS THEODORE R. WEST SHAYNE Y. HUFF, Ph.D. CYNTHIA M. SOROOS PETER W. DINI, Ph.D. JONATHAN M. SPARKS, Ph.D.

TECHNICAL SPECIALISTS CATHERINE M. BISHOP JACOB G. WEINTRAUB CRISTIN E. HOWLEY, Ph.D. JILL ANN MELLO, Ph.D. DEBORAH L. NAGLE, Ph.D.

- * Admitted in TX only ** Admitted in CT only
 - RECEIVED

MAY 1 3 2003

TECH CENTER 1600/2900

Mail Stop DD Commissioner for Patents P.O. Box 1450 Alexandria, VA 22202

Re:

U.S. Patent Application No.: 09/847946

For: ANTI-INFLAMMATORY COMPOUNDS AND USES THEREOF

Inventors: May, Michael J. et al.

Filed: May 2, 2001 Our Ref. No.: PPI-119

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Information Disclosure Statement;
- 2. A copy of the International Search-Report;
- 3. PTO Form 1449;
- 4. Copies of references cited in PTO Form 1449 (47); and
- 5. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22202 on:

May 2, 2003

Giulio A. DeConti Registration No. 31,503 Respectfully submitted,

LAHIVE & COCKFIELD, LLP

Attorney for Applicants Registration No. 31,503

| OIFE W | |
|--------------|----------------|
| MAY 0 9 2003 | PRUCAN |
| RADEN | 1977-80 LIS |

CANT FACSIMILE OF FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO
PPI-119

May 2, 2001

APPLICANT

09/847946

Sheet 1 of 3

LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)

May, Michael J. et al.

GROUP 1646

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | ı | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|------------------|----|-----------------|-------|------------------|-------|----------|-------------------------------|
| Α | 1 | 5,747,641 | 05/98 | Frankel et al. | 530 | 300 | ^ |
| A | 2 | 5,804,374 | 09/98 | Baltimore et al. | 435 | 6 | 7 |
| Α | 3 | 5,804,604 | 09/98 | Frankel et al. | 530 | 324 | 4. C |
| A | 4 | 5,846,743 | 12/98 | Janmey et al. | 435 | 7.8 C | |
| A | 5 | 5,851,812 | 12/98 | Goeddel et al. | 435 | | (A) 3 |
| A | 6 | 5,888,762 | 03/99 | Joliot et al. | 435 | 69.1 | 160 103 |
| A | 7 | 5,939,302 | 08/99 | Goeddel et al. | 435 | 194 | |
| A | 8 | 5,972,655 | 10/99 | Marcu | 435 | 69.1 | 6020 |
| A | 9 | 6,015,787 | 01/00 | Potter et al. | 514 | 12 | 10 |
| A | 10 | 6,030,834 | 02/00 | Chu et al. | 435 | 325 | |
| A | 11 | 6,316,415 B1 | 11/01 | Albrecht et al. | 514 | 18 | |

FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | DATE | Country ' | CLASS | SUBCLASS | TRANS | LATION |
|------|-------------------|-------|-----------|-------|----------|-------|--------|
| | | | | | | YES | NO |
| A12 | WO 98/52614 A2,A3 | 11/98 | wo | | | | |
| A13 | WO 99/29721 A1 | 06/99 | wo | | | | |
| A14 | WO 00/01417 A1 | 01/00 | wo | | | | |
| A15 | WO 00/29427 A2,A3 | 05/00 | wo | | | | |
| A16 | WO 00/31235 A2,A3 | 06/00 | wo | | | | |

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

| A17 | Bower, B.S. et al. "Glicocladium reseum EGIII-like cellulose (partial sequence).", Database A_Geneseq_032802, Accession NO: AAY06332 (6 Sept. 1999). |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A18 | Chu, Z-L. et al., "IKKγ Mediates the Interaction of Cellular IκB Kinase with the Tax Transforming Protein of Human T Cell Leukemia Virus Type 1." The Journal of Biological Chemistry, Vol. 274, No. 22, pages: 15297-15300 (1999) |
| A19 | Delhase, M. et al., "Positive and Negative Regulation of IκB Kinase Activity Through IKKβ Subunit Phosphorylation ." Science, Vol. 284, pages: 309-313 (1999) |
| A20 | Derossi, D. et al. "The third helix of the Antennapedia homeodomain translocates through biological membranes." J. Biol. Chem. Vol. 269, No. 14, pages: 10444-50 (1994). |
| A21 | DiDonato, J.A. et al., "A cytokine-responsive IκB Kinase that activates the transcription factor NF-κB." Nature, Vol. 388, pages: 548-554 (1997) |
| A22 | DiDonato, J.A. <i>et al.</i> , "Mapping of the Inducible IκB Phosphorylation Sites That Signal Its Ubiquitination and Degradation." <i>Molecular and Cellular Biology</i> , Vol. 16, No. 4, pages: 1295-1304 (1996) |

| Examiner | Date Considered |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| *EXAMINER: | ot citation is in conformance with MPEP 609; Draw line through citation Include copy of this form with next communication to applicant. |

| Ŋ | n 9 2003 H | | | Sheet 2 o | of 3 |
|----|--------------------------------------|--------------------------------|----------------|------------|------|
| 11 | APPLICANT FACSIMILE OF FORM PTO-1449 | U.S. DEPARTMENT OF COMMERCE | ATTY DOCKET NO | SERIAL NO. | |
| | REV 🕬 | PATENT AND TRADEMARK OFFICE | DDI 440 | 00/947046 | |

LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)

| ATTY DOCKET NO | SERIAL NO. | |
|---------------------|------------|-----|
| PPI-119 | 09/847946 | |
| APPLICANT | | 1/2 |
| May Michael I et al | *CL | 7/ |

1646 May 2, 2001

FILING DATE

AN ANTANA OTHERS (including Author, Title, Date, Pertinent Pages, Etc.) Ghosh, S. et al., "NF- KB and Rel Proteins: Evolutionarily Conserved Mediators of Imm Responses." Annu. Rev. Immunol. Vol. 16, pages: 225-60 (1998) B2 Harhai, E.W. et al., "IKKy Serves as a Docking Subunit of the IRB Kinase (IKK) and Mediate Interaction of IKK with the Human T-cell Leukemia Virus Tax Protein." The Journal of Biological Chemistry, Vol. 274, No. 33, pages: 22911-22914 (1999) **B3** Hatada, E.N. et al. "NF-κB and the innate immune response." Curr. Opin. Immunol.; Vol. 12, No. 1, pages: 52-8 (2000) B4 Ho. A. et al. "Synthetic protein transduction domains: enhanced transduction potential in vitro and in vivo." Cancer Res. Vol. 61, No.2, pages: 474-7 (2001) Hu, Y. et al., "Abnormal Morphogenesis but Intact IKK Activation in Mice lacking the IKKα Subunit B5 of IkB Kinase." Science, Vol. 284, pages: 316-320 (1999) B6 Jin, D-Y. et al., "Role of Adapter Function in Oncoprotein-mediated Activation of NF-кВ." The Journal of Biological Chemistry, Vol. 274, No. 25, pages: 17402-17405 (1999) B7 Jin, D-Y. et al., "Isolation of Full-Length cDNA and Chromosomal Localization of Human NF-κΒ Modulator NEMO to Xq28." Journal of Biomedical Science, Vol. 6, pages: 115-120 (1999) B8 Корр, E. et al., "Inhibiton of NF-кВ by Sodium Salicylate and Aspirin." Science, Vol. 265, pages: 956-959 (1994) Li, Q. et al., "Severe Liver Degeneration in Mice Lacking the IkB Kinase 2 Gene." Science, Vol. 284, pages: 321-325 (1999) B10 Lindgren, M. et al. "Cell-penetrating peptides." Trends Pharmacol. Sci. Vol. 21, No. 3, pages: 99-103 (2000). B11 May, M.J. et al. "Rel/NF-кВ and IкВ proteins: an overview." Cancer Biology, Vol. 8, pages: 63-73 (1997)B12 May, M.J. et al. "Selective inhibition of NF-κB activation by a peptide that blocks the interaction of NEMO with the IKB kinase complex." Science. Vol. 289, No. 5484, pages: 1550-4 (2000) B13 May, M.J. et al. "Signal Transduction through NF-кВ." Immunolgy Today, Vol. 19, No. 2, pages: 80-88 (1998) B14 Mercurio, F. et al., "IkB Kinase (IKK)-Associated Protein 1, a Common Component of the Heterogeneous IKK Complex." Molecular and Cellular Biology, Vol. 19, No. 2, pages: 1526-1538 (1999)B15 Regnier, C.H. et al., "Identification and Characterization of an IkB Kinase." Cell, Vol. 90, pages: 373-383 (1997) B16 Rothwarf, D.M. et al., "IKK- v is an essential regulatory subunit of the IkB kinase complex," Nature, Vol. 395, pages: 297-300 (1998) B17 Rudolph, D. et al., "Severe liver degeneration and lack of NF-kB activation in NEMO/IKKydeficient mice." Genes & Development, Vol. 14, pages: 854-862 (2000) B18 Siebenlist, U. et al., "Structure, Regulation and Function of NF- κΒ." Annu. Rev. Cell. Biol., Vol. 10, pages: 405-455 (1994) B19 Takeda, K. et al., "Limb and Skin Abnormalities in Mice Lacking IKKa." Science, Vol. 284, pages: 313-316 (1999)

| Examiner | Date Considered |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|] | |
| *EXAMINER: | Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |

MAY 0 9 7000 PPLICANT FACSIMILE OF FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE PATENT AND TRADEMARK OFFICE (Use several sheets if necessary)

ATTY DOCKET NO SERIAL NO.

PPI-119

APPLICANT

May, Michael J. et al.

FILING DATE

GROUP

1646

| | May 2, 2001 1646 |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | OTHERS (including Author, Title, Date, Pertinent Pages, Etc.) |
| C1 | Traenckner, E.B-M. et al., "Phosphorylation of human IκB-α on serines 32 and 36 controls IκB-α proteolysis and NF-κB activation in response to diverse stimuli." <i>The EMBO Journal</i> , Vol. 14, No. 12 pages: 2876-2883 (1995) |
| C2 | Yamaoka, S. et al., "Complementation Cloning of NEMO, a Component of the IkB Kinase Complex Essential for NF-kB Activation." Cell, Vol. 93, pages: 1231-1240 (1998) |
| C3 | Ye, J. <i>et al.</i> , "Regulation of the NF-κB Activation Pathway by Isolated Domains of FIP3/IKKγ, a Component of the IκB-α Kinase Complex." <i>The Journal of Biological Chemistry</i> , Vol. 275, No. 13 pages: 9882-9889 (2000) |
| C4 | Zandi, E. et al. "The IκB kinase complex (IKK) contains two kinase subunits, IKKα and IKKβ, necessary for IκB phosphorylation and NF-κB activation." <i>Cell.</i> Vol. 91, No. 2, pages: 243-52 (1997). |
| C5 | Zhang, S.Q. et al.,"Recruitment of the IKK Signalosome to the p55 TNF Receptor: RIP and A20 Bind to NEMO (IKK γ) upon Receptor Stimulation." Immmunity, Vol. 12, pages: 301-311 (2000) |
| C6 | Zhong, H. et al., "The Transcriptional Activity of NF-kB Is Regulated by the IkB-Associated PKAc Subunit through a Cyclic AMP-Independent Mechanism." Cell, Vol. 89, pages: 413-424 (1997) |
| | |
| | RECEIVED |
| | |
| | MAY 1 3 2003 |
| | TECH CENTER 1600/2900 |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| 1 1 | |

if not in conformance and not considered. Include copy of this form with next communication to applicant.